

### **Remarks**

This Amendment After Final is in response to the Office Action dated **March 19, 2010**. The Office Action restricted out claim 32, alleging the same to be drawn to a non-elected species; rejected claim 31 under 35 USC § 102(b) over Dillon (US 4,849,285); rejected claims 3, 21, 22, 24, and 27 under 35 USC § 103(a) over Houser (US 6,361,559) in view of Clapper (US 5,744,515); and rejected claim 2 under 35 USC § 103(a) over Houser in view of Clapper in further view of Chuter (US 6,293,969).

Claims 3 and 31 are herein amended to provide additional clarity and correct typographical errors.

Claim 2 is herein canceled without prejudice or disclaimer.

In light of the foregoing amendments and following comments, Applicants request reconsideration.

### **Claim Rejections – Section 102**

In rejecting independent claim 31 under § 102(b), at page 6, paragraph 8, the Office Action asserts:

Applicant also argues that Dillon does not anticipate Claim 31 because of the use of ‘consisting of’ language.

However, Claim 31 also still contains ‘comprising’ language.

Without acquiescing to the validity of the rejection, claim 31 is herein amended to recite, in-part, “[a] PTFE based material consisting of: an interpenetrating polymer network consisting of a non-expanded PTFE resin having no node and fibril structure and a solid particulate polymeric component which is incompatible with said non-expanded PTFE resin . . .”

Thus, the PTFE based material consists of an interpenetrating polymer network which consists of a non-expanded PTFE resin . . . and a solid particular polymeric component which is incompatible with said non-expanded PTFE resin. Consequently, Dillon does not anticipate or render obvious claim 3. In particular, as noted in Applicants’ Supplemental Amendment of November 12, 2009, Dillon discloses a “particular ceramic selected from the class

consisting of apatite and tricalcium phosphate and particulate sodium chloride.” Column 2, lines 32-34. The presence of these materials in the composite structure of Dillon renders the material disclosed in Dillon different from that claimed in claim 31. *See MPEP § 2111.03 (“The transitional phrase “consisting of” excludes any element, step, or ingredient not specified in the claim.”* (citing *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931))). As such, Applicants request withdrawal of the rejection.

### **Claim Rejections – Section 103**

In rejecting claims 3, 21, 22, 24, and 27-30, the Office Action asserts, “Houser et al teach a vascular graft . . . comprising an extruded composite of materials that are selected from a group including silicone and PTFE . . .” Page 3, paragraph 6. The Office Action further asserts, “Clapper teaches a room – temperature vulcanizing silicone in the making of a vascular graft . . .” Page 4, paragraph 6. And, although the Office Action notes that Houser fails to disclose a composite that is an interpenetrating polymer network, *id*, the Office Action nonetheless asserts:

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a room - temperature vulcanizing silicone in Houser et al, therefore an interpenetrating polymer network, because the silicone is crosslinked, in order to obtain a graft that closely approximates natural vessels as taught by Clapper.

*Id.* Applicants disagree.

First, the rejection is deficient because the proposed combination does not render these claims obvious in that it would not necessarily result in an interpenetrating polymer network.

Although Houser discloses a composite of materials, Houser does not discuss the structure of the composite material. It is unknown from Houser, for example, whether the composite is layered – having one material on top of another – a homogeneous mixture, or formed in some other arrangement. Moreover, the Office Action has not shown that a

"composite" of PTFE and the silicone of Clapper necessarily results in an interpenetrating polymer network. Therefore, even if, for the sake of argument only, the proposed combination were obvious, the Office Action has not met its burden of showing that the resulting product would have an interpenetrating polymer network as required by the claims.

Second, the rejection is deficient in that the applied prior art does not present a finite and small number of options.

Houser discloses a host of materials and potential composites made from those materials. Specifically, Houser states, “[s]ynthetic bypass grafts may be manufactured by extruding, injection molding, weaving, braiding, or dipping polymers such as PTFE, expanded PTFE, urethane, polyamide, nylon, silicone, polyethylene, collagen, polyester or composites of these representative materials.” column 7, lines 3-7. Thus, Houser discloses five methods of manufacturing, nine materials, and a host of “composites” of those materials.

In order to establish obviousness, however, the prior art must present a finite and small number of options. *See Ortho-Mcneil Pharmaceutical Inc. v. Mylan Laboratories Inc.* 86 USPQ2d 1196, 1201 (Fed. Cir. 2008). The court in *Ortho-Mcneil* stated:

Mylan cites *KSR International Co. v. Teleflex Inc.*, for the proposition that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” 127 S. Ct. 1727, 1742 (2007). The record, however, shows that even if an ordinarily skilled artisan sought an FBPase inhibitor, that person would not have chosen topiramate. Moreover this invention, contrary to Mylan’s characterization, does not present a finite (and small in the context of the art) number of options easily traversed to show obviousness. The passage above in *KSR* posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness. In this case, the record shows that a person of ordinary skill would not even be likely to start with 2,3:4,5 di-isopropylidene fructose (DPF), as Dr. Maryanoff did. Beyond that step, however, the ordinarily skilled artisan would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate. Even beyond that, the ordinary artisan in this field would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes). In sum, this clearly is not the easily traversed, small and finite number of alternatives that KSR suggested might support an inference of obviousness. *Id.* at 1742.

In other words, Mylan's expert, Dr. Anderson, simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious. Of course, this reasoning is always inappropriate for an obviousness test based on the language of Title 35 that requires the analysis to examine "the subject matter as a whole" to ascertain if it "would have been obvious at the time the invention was made." 35 U.S.C. § 103(a) (emphasis added).

*Id.*

Out of the realm of possibilities of materials and arrangements disclosed in Houser, the Office Action has not established a finite and small number of options.

Therefore, the Office Action's assertion – that the combination of Houser and Clapper renders claims 3, 21, 22, 24, and 27-30 obvious – is erroneous. Out of the realm of possibilities, the Office Action has not established a finite number of options, and has not established that one of ordinary skill in the art would select the materials and arrangement of the extrudate of Applicants' claims. Consequently, the Office Action has failed to establish a *prima facie* case of obviousness and Applicants request withdrawal of the rejection.

With further regard to independent claim 3 and the Office Action's rejection thereof, it is unclear where Houser discloses a "porous tubular extrude having a bulk density of between 0.2 and 0.5 g/cc," as is therein claimed. Although the Office Action asserts that Houser discloses such an extrudate, the Office Action has not indicated where, in the disclosure of Houser, an extrude with a bulk density of the recited range is disclosed. Moreover, the Office Action has not provided any reasoning why such a bulk density would be obvious in light of the disclosure of Houser. *See MPEP §§ 2142 and 2143.01* ("rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.") (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006))). For this additional reason, Applicants request withdrawal of the rejection of independent claim 3 and the claims depending therefrom.

The Office Action further rejected claim 2 under 35 USC § 103(a) over Houser in view of Clapper in further view of Chuter (US 6,293,969). Dependent claim 2 is herein canceled without prejudice or disclaimer, thereby mooting the rejection.

### **Conclusion**

Based on at least the foregoing remarks, Applicants request allowance of claims 3, 21, 22, 24, and 27-31. Favorable consideration and prompt allowance of these claims is earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below.

Respectfully submitted,

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